

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 127912 CO/MG/HB	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CH02/00136	International filing date (day/month/year) 06/03/2002	Priority date (day/month/year) 09/03/2001
International Patent Classification (IPC) or national classification and IPC A61B17/70		
Applicant CO-LIGNE AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22/07/2002	Date of completion of this report 21.02.2003
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Storer, J Telephone No. +49 89 2399 7247



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CH02/00136

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

2-6 as originally filed

1,1a as received on 14/09/2002 with letter of 12/09/2002

Claims, No.:

1-9 as received on 27/01/2003 with letter of 24/01/2003

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

- 2. Citations and explanations**
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The application refers to a longitudinal implant and connecting device, wherein the implant is comprised of a filament or fibre composite material and the connecting device is made of a harder material than the implant. The closest prior art is EP-A-0637437 (D1), which should have defined the preamble of claim 1.

Claim 1 is not correctly delimited with respect to D1 as required by Rule 6.3(b) PCT. The pre-characterising portion of claim 1 should have been: "longitudinal implant (1, 17, 30) and connecting device (6, 7, 20, 21) wherein said longitudinal implant (1, 17, 30) is fastened to bones on either side of the damaged area through said connecting device (6, 7, 20, 21), said implant (1, 17, 30) being comprised of a filament or fibre composite material wherein the filaments or fibres (18, 19) are oriented to resist biomechanical forces and said connecting device (6, 7, 20, 21) being made of material harder than said longitudinal implant (1, 17, 30), characterised in that" The subject-matter of this excerpt is disclosed in D1 on page 3, lines 39-44, page 4, lines 30-32, page 4, line 52 to page 5, line 4, page 7, lines 14-19 and figure 1.

The problem addressed by the invention is how to provide a suitably robust longitudinal implant with improved fixation stability between the implant and the connecting device.

The problem is solved by arranging the connecting device to squeeze and lock the longitudinal implant into position both by depression of the implant caused by the squeezing and increased friction between the harder material of the connecting device and the composite material of the implant and by providing a longitudinal implant wherein the filaments or fibres are aligned lengthwise, so that the squeezing will not change their strength characteristics.

Claim 1 is novel and is considered to be inventive since the available prior art does not suggest combining such a longitudinal implant (an elongated plate, rod or rail, the plate having a longitudinal slot extending along a substantial portion of its length, wherein the filaments or fibres are aligned lengthwise) with a connecting device which locks the implant into position by depressing the implant. The industrial applicability of the

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invention is self evident, therefore claim 1 satisfies the conditions of Article 33(2)-(4) PCT. Since claims 2-9 are dependent on claim 1, these likewise satisfy the requirements of the PCT with respect to novelty, inventive step and industrial applicability.

Dependent claims 2-9 do not unambiguously refer to the same subject-matter as claim 1 and therefore a lack of clarity arises in contravention of Article 6 PCT. The subject-matter of claims 2-9 should have been "longitudinal implant and connecting device".

The description has not been brought into line with the claims as required by Rule 5.1(a)(iii) PCT. Furthermore, the description and drawings contain embodiments which are no longer covered by claim 1 (in particular, the embodiment shown in figure 13 and those described on page 6, lines 11 to 15) and which should have been deleted (Rule 5.1(a)(iii) PCT).

Co-Ligne

Longitudinal Implant

This invention relates to a longitudinal implant and connecting device according to the preamble of claim 1.

In some spinal repair situations, the damaged area of the spine is spanned by a slotted plate through which pedicle screws are inserted and fastened to the pedicle bones on either side of a damaged area. This fixes the spatial distance between the pedicle bones and therefore fixes the distance between vertebrae so that the damaged area of the spine can be repaired. In other spinal situations, the damaged area of the spine is spanned by a rod. At least two connectors are slidable along the rod connecting pedicle screws or hooks to the rod. Such a rod and fixation system is disclosed in EP 0 923 908 A (Robert Lange).

WO 97/09000 discloses a bone plate that has conical holes and screws with a conical head. The heads are shaped to fit the holes. The plate and screws are not appropriate to repair damaged areas of the spine.

EP-A-0 637 437 discloses a composite spinal apparatus comprising a composite plate provided with an elongated slot for accommodating a bone screw. A transfer washer interfaces the plate and the bone screw. The transfer washer interfaces with semicircular notches at outer sides of the plate to lock the plate into position.

US-A-4,743,260 discloses a longitudinal stabilization device that is anchored to vertebrae by one screws. The stabilization device has a toothed area that meshes with a toothed area of the screw to lock the longitudinal device into position.

1a

Spinal repair is often times accomplished with hollow cages in which bone fragments are inserted that will grow to an extent to fuse the upper and lower vertebrae together at the damaged area. By fixing and holding the distance between these vertebrae, the bone in the cages will have time to grow and join the vertebrae together.

It is an objective of this invention to provide an elongated implant and pedicle screw or hook fixation system providing an increased stability.

Claims

1. Longitudinal implant and connecting device wherein said longitudinal implant (1, 17, 30) is fastened to bones on either side of a damaged area through that connecting device (6, 7, 20, 21), said implant (1, 17, 30) is comprised of a filament or fiber composite material and said connecting device (6, 7, 20, 21) is made of a material harder than said longitudinal implant (1, 17, 30), characterized in that the connecting device (6, 7, 20, 21) squeezes and locks the longitudinal implant (1, 17, 30) into position both by depression caused by the squeezing and the increased friction between the harder material of the connecting device and the composite material of the longitudinal implant (1, 17, 20), wherein the implant (1, 17, 30) being an elongated plate (1), rod (30) or rail (17), the plate (1) having a longitudinal slot (2) extending along a substantial portion of its length and wherein the filaments or fibers (18, 19) are oriented to resist biochmechanical forces wherein filaments or fibers (18) are aligned lengthwise, so that compression will not change their strength characteristics to any extent even when compressed.

2. Connecting device according to claim 1, wherein the longitudinal implant (1, 17, 30) is made of a carbon filament composite material,

3. Connecting device according to claim 1 or 2, wherein the filaments (18, 19) are encapsulated in a polymer matrix.

4. Connecting device according to claim 3, wherein the filaments (18, 19) are encapsulated in PEEK or PEKEKK.

5. Connecting device according to claim 1, wherein the connecting device (6, 7, 20, 21) comprising a pedicle screw (6)

having an upper section (16c) having a width greater than the width of said slot (2) and exteriorly threaded portion (6b) extending outwardly from said section and extending through said slot (2).

6. Connecting device according to claim 5, wherein an interiorally threaded nut (7) is received by the outer end of said threaded portion (6b) whereby said plate (1) can be grasped between said upper section (6c) and said nut (7) to tightly secure said plate (1) by threading said upper section (6c).

7. Connecting device according to claim 1, wherein said connecting device (6, 7, 20, 21) comprising a screw (6) and a nut (7) which are made of titanium.

8. Connecting device according to claim 1, wherein said implant is a rail (17) having a rectangular cross section.

9. Connecting device according to any one of claims 1 to 8, wherein the filaments (18, 19) are woven.